

## U.S. DEPARTMENT OF DEFENSE

### ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) INFORMATION STATEMENT AND ACKNOWLEDGEMENT

#### IMPORTANT INFORMATION ABOUT ANTHRAX VACCINE

*Please read carefully!*

#### **What is Anthrax?**

Anthrax is an infection caused by germs (bacteria) called *Bacillus anthracis*. Anthrax is a very serious disease. All it takes is a single breath of aerosolized anthrax to inhale enough spores to cause the disease. Anthrax spores are odorless, colorless, and tasteless.

The most deadly form of anthrax, inhalational anthrax, is the form most expected in an anthrax attack. People can be infected with anthrax and not know it, until it's too late. Inhalational anthrax kills 99% of unprotected, untreated people. During the 2001 U.S. outbreak, about half of the people died who contracted inhalational anthrax, despite intensive treatment.

Natural anthrax infection is uncommon in the United States. There is a danger that anthrax could be released as a bio-weapon. Anthrax is a top choice for use as a biological-warfare agent, because anthrax spores are relatively easy to produce in large quantities, easily spread in the air over a large area, and can be stored and remain dangerous for a long time.

The symptoms of inhalational anthrax develop from 1 to 6 days after exposure. These symptoms resemble the common cold or flu: sore throat, mild fever, muscle aches, and tiredness. These mild symptoms can progress very rapidly after a few days to severe breathing problems and death, in some cases.

Anthrax can be prevented through the use of anthrax vaccine (discussed below).

#### **What Is The Anthrax Vaccine?**

Anthrax vaccine contains proteins filtered from cultures of anthrax bacteria. The principal ingredient is a protein called "protective antigen" or PA. This protein is common to all anthrax bacteria and allows the vaccine to protect against all forms of anthrax.

You cannot get anthrax (infection from anthrax bacteria) from anthrax vaccination.

The same anthrax vaccine being offered to you was given to more than 800,000 American service members since 1998. The anthrax vaccine being offered to you has

been licensed by the Food & Drug Administration (FDA) since 1970. The FDA specifically authorized the manufacturer (BioPort Corporation) to release the lot (batch) of anthrax vaccine being offered to you. Anthrax vaccine used by the Department of Defense passes all tests required by the FDA.

Based on human and animal data, the National Academy of Sciences concluded in a March 2002 report that anthrax vaccine is “an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *B. anthracis*.”

The benefit of anthrax vaccine to you could be very low or very high. Anthrax vaccination would have little value to you personally, if you are not exposed to anthrax as a bio-weapon. Anthrax vaccination could have great value to you personally, if you are exposed to anthrax as a bio-weapon.

### **Who Should Be Vaccinated?**

While the Department of Defense has no specific information to indicate how likely anthrax could be used as a weapon in the immediate future, it does recognize that bioterrorism has become a potential health risk to Americans living at home or living abroad in higher-threat areas. As part of the Nation’s preparedness against the bioterrorism threat, the Department of Defense (DoD) has been vaccinating selected service members since 1998. Laboratory workers have been vaccinated against anthrax for many years. Anthrax vaccine is now being made available to you, to help protect you.

### **Who Should Not Get Anthrax Vaccine?**

Some people should not get anthrax vaccine, including:

- Pregnant women or women uncertain whether they are pregnant.
- People whose immune system is not working fully (e.g., due to disease, medication, or radiation). Examples: HIV/AIDS, cancer, organ transplant, immune deficiency.
- People who recovered from anthrax infection of the skin (cutaneous anthrax).
- Anyone who had problems after previous doses of anthrax vaccine or who is allergic to anthrax vaccine or any of its components.
- Anyone else whose physician recommends be exempt from anthrax vaccination for medical reasons.
- The safety and effectiveness of anthrax vaccine in people younger than 18 or more than 65 years of age has not been studied specifically. Therefore, anthrax vaccine is generally not recommended for these people.

## **Dosage**

Anthrax vaccine is administered by injecting the vaccine about ½” inch into the skin (a subcutaneous injection). The vaccine is given in a series of 6 doses over 18 months. The second and third doses are each given 2 weeks after the previous dose. The fourth dose is given 5 months after the third dose. The fifth and sixth doses are given 6 months after the previous dose. Annual booster doses are given for sustained immunity.

## **What Side Effects Are Expected After Anthrax Vaccination?**

Most people have normal, usually mild, reactions after anthrax vaccination. A burning sensation often occurs immediately after getting anthrax vaccine and can last about a minute. Like other vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site.

Up to 30% of men and 60% of women report small injection-site reactions (smaller than 1 inch), but these reactions usually last only a few days. For both genders, between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur in about 1% of vaccine recipients. A lump at the site occurs commonly, up to 50% of the time, lasting for a few weeks.

Beyond the injection site, 5% to 35% may notice such symptoms as muscle or joint aches, headaches, rashes, chills, low-grade fever or nausea. These symptoms usually go away in less than a week. Over-the-counter medications before or after the anthrax vaccine may help reduce bothersome symptoms.

Any vaccine can cause serious reactions, including those requiring hospitalization or medical care. Severe allergic reactions occur less than once per 100,000 doses.

Anthrax vaccine has been used for over 30 years. No serious adverse events with prolonged illness have been detected during this time. In its March 2002 report, the National Academy of Sciences found that anthrax vaccine causes side effects “comparable to those observed with other vaccines regularly administered to adults.” This report found no evidence that people face an increased risk of serious adverse events immediately after receiving anthrax vaccine or over the longer term.

## **What Treatment or Compensation is Available for Adverse Effects?**

For DoD civilian employees or contractor personnel receiving anthrax vaccine under the DoD Anthrax Vaccine Immunization Program (AVIP), if you believe you have an

adverse reaction requiring medical attention, you should go to a military treatment facility or occupational health clinic for an initial assessment and any needed emergency care, consistent with any applicable occupational health program procedures. Your supervisor can provide you additional information.

For DoD civilian employees receiving anthrax vaccine under the DoD Anthrax Vaccine Immunization Program based on employment (for example, as a laboratory worker), an adverse reaction would entitle the employee to worker's compensation coverage under the Federal Employees' Compensation Act. This will cover additional medical treatment and compensation for inability to work, if needed. Standard agency procedures for work-related injuries should be followed. Your supervisor can provide you additional information.

For contractor personnel receiving anthrax vaccine under the DoD Anthrax Vaccine Immunization Program based on employment, worker's compensation coverage is based on the State worker's compensation program. This will determine rights and procedures concerning further medical treatment and compensation for inability to work. Your employer or State worker's compensation agency can provide you additional information.

For other individuals receiving anthrax vaccine, including anyone who is not receiving it based on his or her employment status, medical care for any adverse events is based on your medical program coverage. For beneficiaries of the TRICARE program or Federal Employees Health Care Program, your comprehensive health care coverage includes treatment for any adverse events, within your normal health plan terms. There is no compensation program for lost wages or any other losses.

### **Other Precautions & Warnings**

If you have a mild illness at the time vaccination is scheduled, you can still take the vaccine. However, if you are moderately or severely ill, you should wait to get the vaccine. You should advise the doctor or health practitioner administering the vaccine if you are ill.

If you become sick after anthrax vaccination, seek medical care as appropriate for the condition. Inform your healthcare provider that you recently received anthrax vaccine. Extensive additional information is available about experience with anthrax vaccine. If you would like additional information, we can provide it to you.

### **Monitoring for New Side Effects of Anthrax Vaccine**

We conduct an ongoing evaluation of vaccine safety. Sometimes, illness occurs after vaccination that may or may not be caused by the vaccine. By evaluating large populations, previously unrecognized or rare vaccine reactions may be identified.

Please report any medical problems after any vaccination to your healthcare provider, so they can be reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS is operated by the FDA and the Centers for Disease Control & Prevention (CDC). We encourage you to work with your healthcare provider in completing reports to VAERS. You may also directly report these events to VAERS yourself. You can submit VAERS reports on-line at [www.vaers.org](http://www.vaers.org) or call 800.822.7967.

### **Vaccination is Voluntary**

For civilian and contract personnel not subject to mandatory immunization, the decision to receive anthrax vaccination is completely voluntary. You may decline the vaccination with no adverse consequences or loss of any rights and benefits. If you have questions, please contact your local healthcare provider, your supervisor, or the Commander of the unit to which you are assigned.

**Please keep these pages for your records.**

**Please sign the vaccine administration acknowledgement on the following page.**

**Please return the signed page to the healthcare provider  
who administers the vaccine to you.**

**ACKNOWLEDGEMENT BEFORE RECEIVING ANTHRAX VACCINE**

I have read or have had explained to me the information about anthrax and anthrax vaccine on pages 1 through 5 of this document. I understand:

- The benefits and risks of anthrax vaccination.
- The conditions (including pregnancy or possible pregnancy) that would exclude me from receiving anthrax vaccination.
- The expected side effects from anthrax vaccination.
- The full shot series of 6 shots over 18 months (3 in the first 4 weeks).
- Anthrax vaccination is voluntary for me.

I request anthrax vaccination.

Signature of person \_\_\_\_\_  
to receive vaccination:

Date: \_\_\_\_\_

Information about the person receiving the vaccination. (Please print.)

Last Name \_\_\_\_\_ First \_\_\_\_\_ Middle \_\_\_\_\_

Birth date \_\_\_\_\_ (mm/dd/yyyy).

Social Security Number \_\_\_\_\_

Street \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_

Zip or Postal Code \_\_\_\_\_ Country \_\_\_\_\_

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Clinic/Health Unit Information. (Please Print.)

Clinic Name \_\_\_\_\_

Street \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_

Postal Code \_\_\_\_\_ Country \_\_\_\_\_ Vaccination Date \_\_\_\_\_

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**PRIVACY ACT STATEMENT:**

AUTHORITY: Sections 113, 3013, 5013, and 8015 of Title 10, United States Code and Executive Order 9397.

PRINCIPAL PURPOSE: To document your understanding of important information about anthrax and anthrax vaccine and that you voluntarily agree to receive it.

ROUTINE USES: None.

DISCLOSURE: Voluntary, but failure to do so may prevent the Department of Defense from giving you the anthrax vaccination.